IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8973**

Bartle, J. November 21, 2012

Sydney Davis ("Ms. Davis" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D., F.A.C.C. Based on an echocardiogram dated March 19, 2002, Dr. Boxberger attested in Part II of claimant's Green Form that Ms. Davis suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings claimant would

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

be entitled to Matrix A-1, Level II benefits in the amount of $444,159.[3]

In the report of claimant's echocardiogram, the reviewing cardiologist, Mark Burton, M.D., stated that claimant had "mild tricupsid regurgitation with a right ventricular systolic pressure that is elevated at 48 consistent with mild pulmonary hypertension." Pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure > 40 mm Hg measured by cardiac catheterization or > 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See Settlement Agreement § IV.B.2.c.(2)(b)i). Dr. Burton also observed that claimant's "left ventricular function is normal, ejection fraction of 60%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%."[4] Id. at § IV.B.2.c.(2)(b)iv).

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3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.C.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issues are claimant's pulmonary hypertension and ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim.

4. Claimant also submitted an echocardiogram report prepared in May, 2002 by Dr. Boxberger based on her March 19, 2002 echocardiogram. In this report Dr. Boxberger stated that claimant had "[m]ild resting pulmonary and hypertension based on

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In December, 2003, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the attesting physician's findings that Ms. Davis had pulmonary hypertension secondary to moderate mitral regurgitation or a reduced ejection fraction in the range of 50% to 60%. Specifically, Dr. Gillespie measured claimant's pulmonary artery systolic pressure at 39.2 mm Hg and stated that "[t]here were 2 very clear jets measured to be 2.6 and 2.7 m/s. The last jet measured was an incomplete envelope and could not be measured accurately. Visually it appeared less than 3 m/s even if extrapolated, but I would not have attempted to measure this incomplete jet." In addition, Dr. Gillespie observed that claimant's left ventricular ejection fraction was "qualitatively more than 65%."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5]

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4. (...continued)
tricuspid regurgitation, estimated pulmonary artery systolic pressure peak of 48 mm of Mercury" and a "[n]ormal [left ventricular] size, [left ventricular ejection fraction is] 60%."

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute
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In contest, claimant submitted affidavits from Dr. Boxberger, Roger W. Evans, M.D., F.A.C.P., F.A.C.C.,[6] G. Whitney Reader, M.D., F.A.C.P., F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Boxberger confirmed his previous findings that claimant had pulmonary hypertension with a peak systolic artery pressure of 48 mm Hg and a reduced ejection fraction of 60%. Dr. Evans stated that claimant's echocardiogram showed "an ejection fraction of 60%" and "a peak systolic pulmonary artery pressure, based on the tricuspid insufficiency jet, of 46-50 mmHg." In addition, Dr. Reader and Dr. Francisco both concluded that Dr. Boxberger had a "reasonable medical basis" to find that claimant's echocardiogram demonstrated a reduced ejection fraction in the range of 50% to 60%. Claimant argued, therefore, that she had established a reasonable medical basis for her claim because four Board-Certified Cardiologists independently agreed that she had at least one complicating factor that would qualify her for Matrix Benefits. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his **personal opinion** ... and the 'reasonable medical basis' standard." (Emphasis in original.)

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5. (...continued)
that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Davis.

6. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed in excess of 322 Green Forms on behalf of claimants seeking Matrix Benefits. See PTO No. 8412 (Mar. 9, 2010).

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On November 17, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4142 (Nov. 17, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 24, 2005, and claimant submitted a sur-reply on February 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a cases such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation or a reduced ejection fraction. See id. Rule 24. Ultimately if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Davis reasserts the arguments she made in contest; namely, that the opinions of Dr. Boxberger, Dr. Evans, Dr. Reader, and Dr. Francisco provide a reasonable medical basis for finding that she had at least one of the complicating factors needed to qualify for a claim for Matrix Benefits. Claimant also contends that the concept of inter-reader variability accounts for the differences between the opinions provided by her physicians and those of the auditing

cardiologist, Dr. Gillespie. Regarding her ejection fraction, claimant argues that there is an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Rule, 16% when using the wall motion index, and 19% when using subjective visual assessment. Ms. Davis thus contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that an ejection fraction is as high as 79%, a finding of an ejection fraction of 60% by an attesting physician is medically reasonable.[8]

In response, the Trust argues that the opinions of Dr. Evans, Dr. Reader, and Dr. Francisco do not establish a reasonable medical basis for the attesting physician's findings because they do not address Dr. Gillespie's findings and "merely reiterate Dr. Boxberger's finding[s] in a conclusory fashion." The Trust also contends that inter-reader variability does not establish a reasonable medical basis for the claim because "Dr. Gillespie's findings and specific explanations simply cannot be attributed to inter-reader variability."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's findings

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8. Ms. Davis also responds to the Trust's argument that claimant's additional expert reports should be disregarded because Audit Rule 18(b) prohibits the submission of more than one expert report. We disagree. We previously have declined to impose a limitation on the number of verified expert opinions that may be submitted by a claimant. See, e.g., PTO No. 7111 at 6 n.9 (Apr. 12, 2007).

of pulmonary hypertension secondary to moderate or greater mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Specifically, Dr. Abramson determined that:

> In reviewing the transthoracic echocardiogram, it is a good quality study, with normal systolic function by visual estimation. I chose to measure three ejection fractions using Simpson's biplane method of discs. I calculated ejection fractions of 68%, 69% and 69%. These ejection fractions are all clearly greater than 60%.
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> There are two accurately measured tricupsid regurgitant jets in this study which calculate to a pulmonary artery systolic pressure of 37 and 39 mmHg. The third jet that the technologist measured, in the apical-4-chamber view, is an incomplete envelope which the technologist arbitrarily measured at too high a value. This jet does not have a measurable velocity. Thus, the [pulmonary artery systolic pressure] in this patient is less than 40 mmHg.

In response to the Technical Advisor Report, Ms. Davis argues that Dr. Abramson's opinion should be disregarded because she used the modified Simpson's Rule rather than the "standard" Simpson's Rule, the wall motion index, or subjective visual assessment in her evaluation of claimant's ejection fraction, which she contends are "the three [3] generally accepted methods for determining the ejection fraction."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, although claimant submitted the reports of several cardiologists, neither claimant nor her experts identified any particular error in the findings of the auditing cardiologist and the Technical Advisor. The

auditing cardiologist's determined that claimant's pulmonary artery systolic pressure was 39.2 mm Hg with two "very clear jets measured to be 2.6 and 2.7 m/s" and that claimant's ejection fraction was in the range of 65% to 70%.[9] In addition, the Technical Advisor concluded that "[t]here are two accurately measured tricuspid regurgitant jets ... which calculate to a pulmonary artery systolic pressure of 37 and 39 mmHg" and that claimant's ejection fraction was measured at 68%, 69%, and 69%.[10] Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for Dr. Boxberger's representation that Ms. Davis had a reduced ejection fraction is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and Technical Advisor both

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9. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

10. We will not accept claimant's invitation to disregard the Technical Advisor's opinion because she used the modified Simpson's method of discs rather than the "standard" Simpson's method. First, claimant does not provide any support for her argument that the standard Simpson's method is preferred over the modified method. Second, she does not submit that a different result would obtain had the standard Simpson's method been used.

concluded that claimant's echocardiogram demonstrated an ejection fraction greater than 65%. This is especially true where the Technical Advisor stated that "[t]here is no reasonable medical basis for the Attesting Physician to state that the Claimant's ejection fraction is in the range of 50% to 60%" based on her own measurements of 68%, 69%, and 69%. Adopting claimant's argument that inter-reader variability would expand the range of an ejection fraction by as much as ±19% would allow a claimant to recover Matrix Benefits with an ejection fraction as high as 79%. This result would render meaningless this critical provision of the Settlement Agreement.

We also are not persuaded by claimant's assertion that the differences in opinion regarding the level of her peak systolic pulmonary artery pressure are due to inter-reader variability. The auditing cardiologist and the Technical Advisor again agreed that there were two tricuspid regurgitant jets that, when calculated correctly, resulted in peak pulmonary systolic artery pressure measurements well below the 45 mm Hg that would qualify a claimant for Matrix Benefits. Additionally, Dr. Gillespie and Dr. Abramson determined that the last jet measured by the technologist was incomplete and therefore could not be measured properly. Claimant did not submit any support for her argument that inter-reader variability applies to a determination of pulmonary hypertension and fails to challenge or account for the Technical Advisor's determination that "[t]here is no reasonable medical basis for finding that this Claimant has

pulmonary hypertension secondary to moderate mitral regurgitation" because claimant's "pulmonary artery systolic pressure ... is less than 40 mmHg by echocardiography."

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had pulmonary hypertension secondary to moderate or greater mitral regurgitation or a reduced ejection fraction. Therefore, we will affirm the Trust's denial of the claim of Ms. Davis for Matrix Benefits.